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1. Introduction

1.1 Organization Overview

This document is organized into seven main sections.

- **Section One (Introduction)** discusses the background, scope, and organization.
- **Section Two (Getting Started)** contains instructions on connecting to the system, logging on, requesting accounts, and navigation from the home page.
- **Section Three (Settings for All Users)** provides information on system wide settings available to all POCA user roles.
- **Section Four (Advanced Settings for Business and System Admin. Users)** describes information on system wide settings available to System Administrators and Business Administrators users.
- **Section Five (Advanced Settings – System Administrators)** provides information on system wide settings accessible to the System Administrators user group.
- **Section Six (Advanced Settings – Business Administrators)** provides information on system wide settings accessible to the Business Administrators user group.
- **Section Seven (Drug Name Searches – All Users)** provides information about how to perform drug name searches.

1.2 Background

A vital part of the Food and Drug Administration (FDA) and Center for Drug Evaluation and Research (CDER)'s mission is to develop new standards to prevent medication errors due to proprietary name confusion. The Office of Surveillance and Epidemiology (OSE), Division of Medication Error Prevention and Analysis (DMEPA) contributes to this effort by evaluating all proprietary names submitted to CDER for similarity to other marketed names. In December 1999, the Institute of Medicine (IOM) Report recommended testing of proposed proprietary names to prevent confusion and medication errors with existing drug names. The Quality Interagency Coordination Task Force (QuIC) reporting to the President in February 2000 endorsed the IOM recommendation.

In response to these reports, FDA devoted greater resources to the area of drug name confusion analysis. Proprietary name confusion may stem from the manner in which a name is pronounced or scripted. The Phonetic and Orthographic Computer Analysis System (POCA) is a web application developed to determine written (orthographic) and spoken (phonetic) similarities between proposed drug names.

1.3 Document Scope

This User Guide provides information about all of the features in the application. It is not a technical developer's manual, nor does it provide in-depth information on the database or operating systems.

This document was written for the FDA and refers to three types of users, namely *Safety Evaluator*, *Business Administrator*, and *System Administrator*. The scope of their access to the system is as described below.

Safety Evaluator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches
- Personal settings

Settings for safety evaluators include as per the screen below:

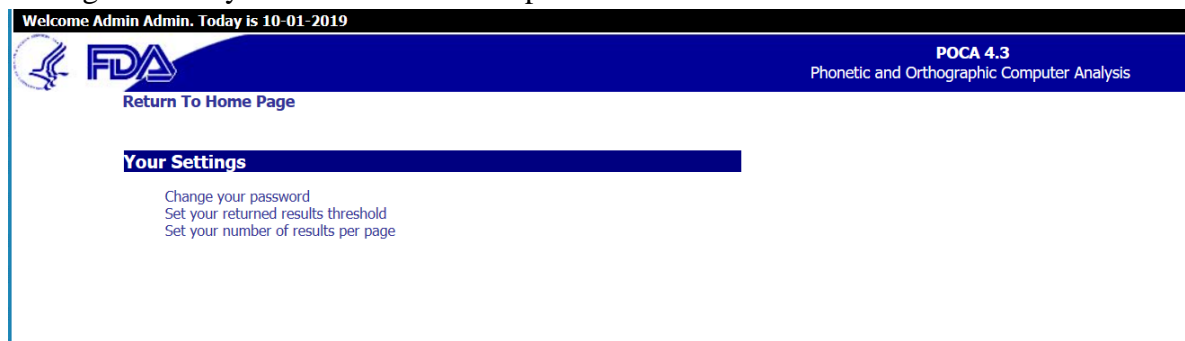


Figure 1: Settings Page for Safety Evaluators

Business Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches
- Personal settings
- Manually Add Drug Names To Database
- Delete Drug Names from Database
- Add/Edit users
- UAR Report

Settings for business administrators include menu options as shown in Figure 2 below:

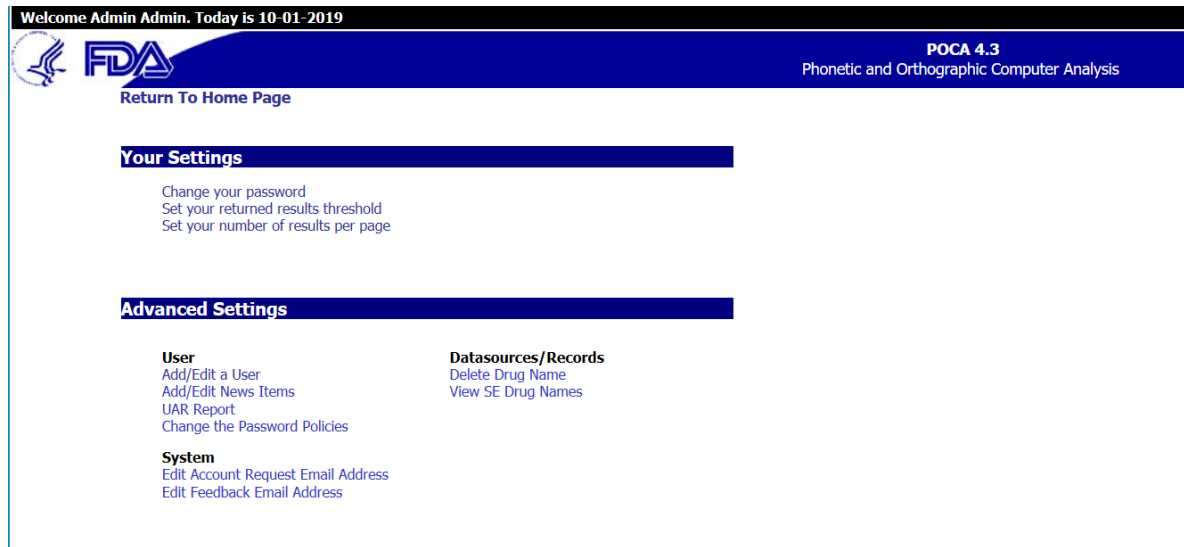


Figure 2: Settings Page for Business Administrators

System Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Search
- Personal settings
- Data sources Maintenance
- Add/Edit users
- UAR Report

Settings for System Administrators include menu options as shown in Figure 3 below:

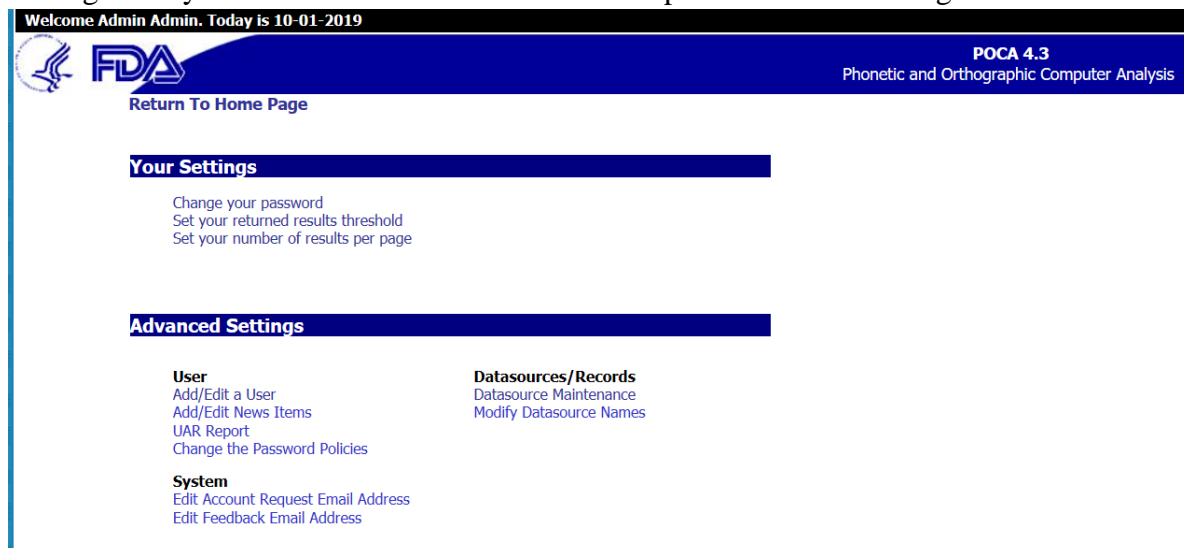


Figure 3: Settings Page for System Administrators

2 Getting Started

To access POCA, open your web browser (Internet Explorer, Chrome, Firefox or any other browser). Internet Explorer is opened by double clicking on the IE browser icon on your desktop or by selecting Start, Programs, and Internet Explorer from the start menu. In the address bar of your web browser, type the universal resource locator (URL) for POCA as <http://poca.pub.com/>. The Login screen will appear as shown in Figure 4 below.



Disclaimer

This is a Federal computer system and is the property of the United States Government. It is for authorized use only. Users (authorized or unauthorized) have no explicit or implicit expectation of privacy.

Any or all use of this system and all files on this system may be intercepted, monitored, recorded, copied, audited, inspected, and disclosed to authorized site, Food and Drug Administration, and law enforcement personnel, as well as authorized officials of other agencies, both domestic and foreign. By using this system, the user consents to such interception, monitoring, recording, copying, auditing, inspection, and disclosure at the discretion of authorized site or Food and Drug Administration personnel.

Unauthorized or improper use of this system may result in administrative disciplinary action and civil and criminal penalties. By using this system you indicate your awareness of and consent to these terms and conditions of use.

Figure 4: Login Screen

You will need a user account to access POCA. If an account has been created for you, enter your user ID and password and left click the Login button.

2.1 Resetting Your Password

If you do not remember your password, click the “Reset Password” link. The *Reset Password* screen, shown below, will be displayed as shown in Figure 5 below.



Figure 5: Reset Password Screen

Type your username and click “Submit.” POCA will assign a temporary password to your account and send you an automated e-mail message with the temporary password. You will be required to change your password upon login.

2.2 Changing Your Password

If you wish to change your password, click on the “Change Password” link on the POCA login page. The *Change Password* screen will be displayed, as shown in Figure 6 below.

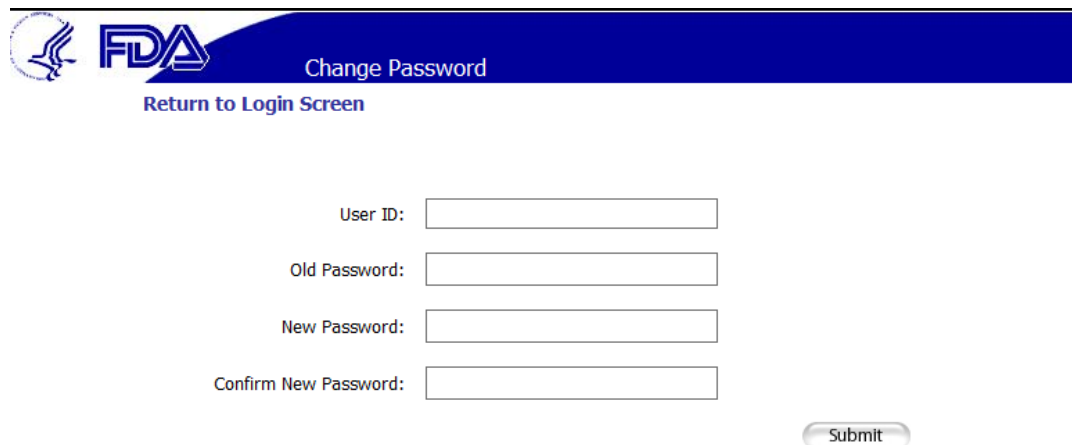


Figure 6: Change Password Screen

Enter your current login credentials in the text boxes labeled “User ID” and “Old Password” to allow POCA to verify your identity. Enter your desired password into the textboxes labeled “New Password” and “Confirm New Password,” and click the “Submit” button. If the current login information you entered is incorrect, your passwords do not match, or your new password does not comply with POCA password requirements, you will be asked to correct your inputs.

2.3 Requesting an Account

If you do not have a POCA account, you may request the POCA account by clicking

on the “Request Account” link on the login screen. The *Request an Account* screen will be displayed as shown in Figure 7 below.

Figure 7: Request Account Screen

Enter your name and email address in the text boxes provided and click the “Submit” button. An email will be sent to a POCA administrator stating that a POCA account is being requested for you. The POCA administrator will add your account to POCA with the Safety Evaluator user role unless a different role is requested. You will receive an email from POCA application after your account is created. At that point, you may log in by typing <http://poca.pub.com> in your browser. Upon successful log in, the home page is displayed as shown in Figure 8 below.

2.4 Home Page and Navigation

The home page is the main control panel for the system. From the homepage users can access all of the functionality of the system. Specific sections of the home screen and their purpose are described below.

Datasource	Date Updated	Product Count
<input checked="" type="checkbox"/> Drugs At FDA	07-25-2019	21,467
<input checked="" type="checkbox"/> RxNorm	07-09-2019	28,850
<input type="checkbox"/> Suffixes in proper name of biological products	08-29-2019	49

Datasource	Date Updated	Product Count
<input checked="" type="checkbox"/> United States Adopted Names	09-09-2019	608

Figure 8: Home page

2.4.1 Navigation Bar

As illustrated in Figure 9 below, in the top right-hand portion of the home page you will find a navigation bar with links for accessing major parts of the POCA application, such as the home page, search page and settings page. The navigation bar has links for comments and help. This navigation bar is accessible on all POCA pages.



Figure 9: Navigation bar

2.4.2 New Search/Retrieve Archived Search Bar

Another option to navigate to the search page is the “New Search” link located at the top left side of the home page, below the FDA banner as illustrated in the image below.



The *New Search link* is available for all users. This will allow you to search for a drug name.

The *Retrieve Archived Search* link is available for all users. Clicking the link will display a search page that can be used to search for previously conducted searches.

2.4.3 News

News and announcements are displayed for all users. To view more information about the news item, users can click on the news title as shown in Figure 10 below.



Figure 10: News

2.4.4 Drug Name Search

Drug Name Search is displayed for all users as illustrated in Figure 11 below. Users can perform Orthographic, Phonetic or Text searches for any drug name within the selected data sources. More about how to use the *Drug Name Search* feature is described in section 7.

POCA 4.3
Phonetic and Orthographic Computer Analysis

New Search | Retrieve Archived Search

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type: ☒ Orthographic ☒ Phonetic ☐ Text* ☒ Include USAN Stem Search

Datasources:

Datasource	Date Updated	Product Count
<input checked="" type="checkbox"/> Drugs At FDA	07-25-2019	21,467
<input checked="" type="checkbox"/> RxNorm	07-09-2019	28,850
<input type="checkbox"/> Suffixes in proper name of biological products	08-29-2019	49

USAN Stem Datasources:

Datasource	Date Updated	Product Count
<input checked="" type="checkbox"/> United States Adopted Names	09-09-2019	608

Reset Submit

News

POCA Version 4.3
POCA Version 4.3 is deployed

USAN Stem Search for Multiple Drug Names

Open USAN Search Page

Multiple Name Direct Search

Open Direct Search Page

Single Name Direct Search

Candidate Drug:

Comparator Drug:

Reset Submit

Figure 11: Drug Name Search Section in Home Page

2.4.5 Single Name Direct Search

The direct search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and Comparator Drug Names. After entering those 2 drug names and pressing the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed for those 2 drug names as illustrated in Figure 12 below.

Single Name Direct Search

Candidate Drug:

Comparator Drug:

Reset Submit

Combined Score: **77**

Phonetic Score: **73**

Orthographic Score: **81**

Figure 12: Single Name Direct Search section in Home Page

2.4.6 Multiple Name Direct Search

The multiple name direct search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and multiple Comparator Drug Names. After entering the Candidate drug name and multiple Comparator Drug names, click the Submit button. The Combined, Phonetic and Orthographic search result scores will be displayed for Multiple Name Direct Search as illustrated in Figure 13 below.

Welcome Admin Admin. Today is 10-01-2019

POCA 4.3
Phonetic and Orthographic Computer Analysis

Return To Home Page

Multiple Name Direct Search

Candidate Drug:

Comparator Drugs:

Total Drug Name Pairs: 4

Drug Name Pair	Orthographic Score %	Phonetic Score %	Combined Score %
Tinactin - Benzocaine	53	40	46
Tinactin - Benzyl Alcohol	31	17	24
Tinactin - Oxybenzone	22	33	28
Tinactin - Zilactin	81	73	77

Figure 13: Multiple Name Direct Search section in Home Page

2.4.7 Manually Add Drug Name to Database

This functionality, illustrated in Figure 14 below, is only available to users with the designated role of business administrator. It allows business administrators to add drug names manually to “Name Entered by Safety Evaluator” data source. Please see Section 6.1 for more information.

Manually Add Name to Database

Figure 14: Manually Add Name to Database

2.4.8 USAN Stem search for multiple Drug Names

The USAN stem search functionality, illustrated in Figure 15 below, is available to all users. This feature provides users the ability to perform direct searches for the presence of USAN stems within multiple drug names. Click on "Open USAN Search Page" under the "USAN Stem search for multiple Drug Names" section.

USAN Stem Search for Multiple Drug Names

Open USAN Search Page

Figure 15: USAN Stem search

A new page will appear with a *Proposed Drug Names* text field illustrated in figure 16 below.

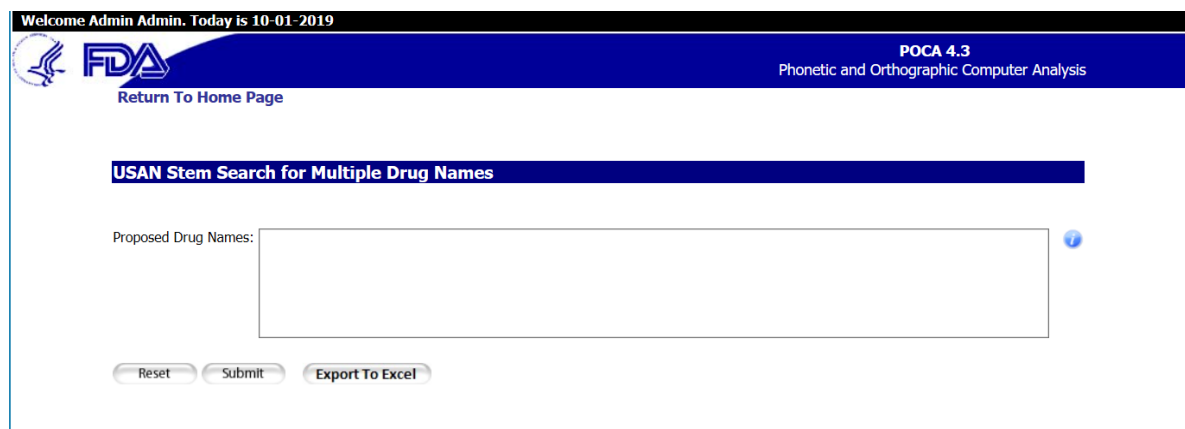



Figure 16: USAN STEM Search Page Ready for Inputs

To use this search function, follow the instructions below:

Enter multiple drug names in the Proposed Drug Names field, and separate each name with a comma. Users may also click on the  icon located to the right of the Proposed Drug Names text field to display a popup message explaining the correct format for entering multiple drug names as illustrated in Figure 17 below:

POCA 4.3
Phonetic and Orthographic Computer Analysis

Return To Home Page

USAN Stem Search for Multiple Drug Names

Proposed Drug Names: sodium, magnesium

Reset Submit Export To Excel

This site says...
Use commas between drug names in the Proposed Drug Names textbox. Do not include drug names that have a comma within the name.
OK

Figure 17: Information icon

Once all names have been entered in the text field, click on the ‘Submit’ button.

The search results will be displayed as illustrated in Figure 18 below:

Welcome Admin Admin. Today is 10-01-2019

POCA 4.3
Phonetic and Orthographic Computer Analysis

Return To Home Page

USAN Stem Search for Multiple Drug Names

Proposed Drug Names: sodium,magnesium

Reset Submit Export To Excel

Total USAN Stem Results for Proposed Drug Names: 2

Drug Name	Affix	Optional Character	Date Created
magnesium	-ium	NA	9/9/2019 1:56:11 PM
sodium	-ium	NA	9/9/2019 1:56:11 PM

Figure 18: USAN STEM Search Page

3. Settings for All Users

All personal settings for your POCA account can be accessed from *Your Settings* section on the *Settings* screen as illustrated in Figure 19 below. To access the *Your Settings* screen, click on the “Settings” link found in the navigation bar. Each role will see

different functionality in Settings page as described in section 1.3.

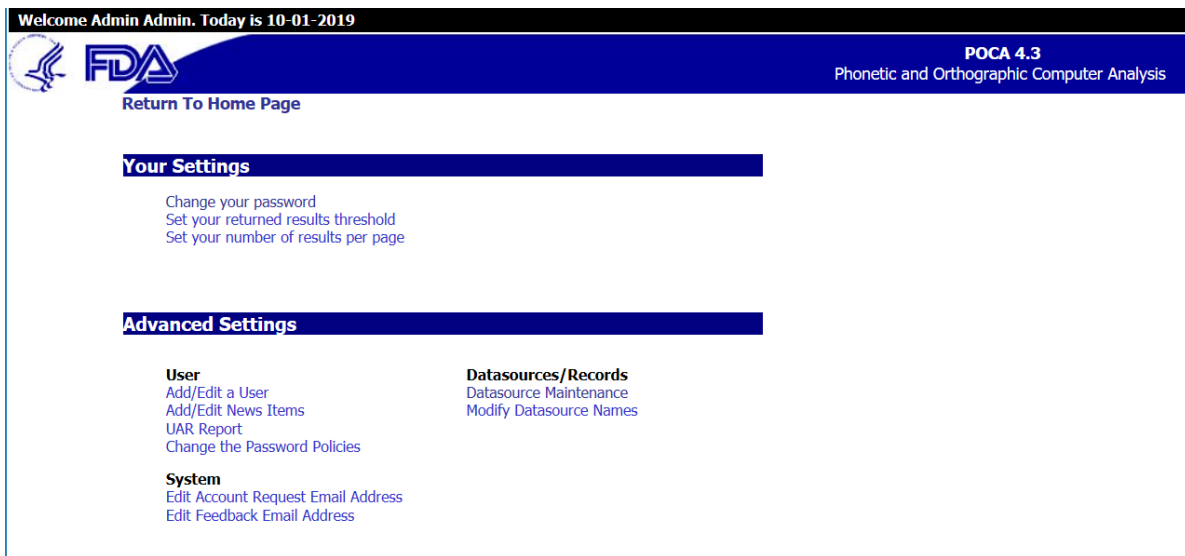


Figure 19: Personal Settings for a System Administrator

The following settings are available to all users.

3.1 Set your Returned Results Threshold

Users can set the threshold for returned results by clicking the “Set your returned results Threshold” option under *Your Settings* as illustrated in Figure 20 below.

Enter a threshold for returned results per module: %

Figure 20: Setting the Threshold for Returned Results

The threshold is the percentage match required for a result to be returned by the search engine. For example: If the threshold is set to 50%, only results with a match percentage of 50% or higher will appear in the result set.

3.2 Set Your Number of Results per Page

POCA allows users to set the default number of results displayed per page by clicking on the “Set Your Number of Results per Page” link under *Your Settings* as illustrated in Figure 21 below. When a user conducts a search, the default number of results will be displayed

per page. If there are more results returned than the default number of results, the user will have the ability to scroll through the pages of results.

Enter the number of results to return per page per module:

Figure 21: Number of results per page

4. Settings for Business and System Administrator Users

Business Administrator and System Administrator user groups have the same advanced settings except for their level of access to ‘Datasource/Records’. The table below shows the level of access for each type of administrator under Datasource/Records:

Administrator User Group	Datasources/Records Level of Access
System Administrator	Datasource Maintenance Modify Datasource Name
Business Administrator	Delete Drug Name View SE Drug Names

The following settings are available to all business and system administrator users.

4.1 Add/Edit a User

To add or edit a user profile, click the “*Add/Edit a User*” link under *Advanced Settings* on the *Settings* page. To access the *Advanced Settings* screen, click on the “*Settings*” link found in the navigation bar. The User Administration page will be displayed as shown in Figure 22 below.

Figure 22: User Administration Page

To add a new user profile, fill out the form that appears under the *Add a new user* heading. All input fields available on the form are described in the table below.

Field Name	Definition/Description	Field Type
User Name	Enter a username for the new account. The username will be used by the user to log in to POCA. This field is required.	Edit
First Name	Enter the first name of the user. This field is required.	Edit
Last Name	Enter the last name of the user. This field is required.	Edit
Email	Enter the email address of the user, and be sure to check for typos. It is important to type this field correctly. The application will use this field to send electronic notifications to the user. This field is required.	Edit
User Group	Select from the list if the user is a <i>Safety Evaluator</i> , <i>Business Administrator</i> or <i>System Administrator</i> .	Pick list

An example of add a *New User* is shown in Figure 23 below:

Add a new user:

User Name:

First Name:

Last Name:

Email:

User Group:

Figure 23: Add User Page

When editing a user profile, please note that there are two pick lists for existing user profiles, one for enabled accounts, and another for disabled accounts as previously illustrated in Figure 22 above. You can choose an account to edit by pressing the dropdown arrow and selecting the user profile you wish to edit so that it displays in the text field and then clicking the “Edit User” button. Once a user is selected for editing, the *Edit User* form, seeded with all available information, will display as illustrated in Figure 24 below..

Welcome Admin Admin. Today is 10-02-2019

FDA **POCA 4.3**
Phonetic and Orthographic Computer Analysis

[Return to User Administration](#)

Edit User

User Name: Admin

First Name:

Last Name:

Email:

User Group:

Figure 24: Edit User Screen

The *Edit User* form allows the editing of the First Name, Last Name, Email, and User Group associated with a user. When you are done editing these fields, click “Update User” to submit these changes to the POCA database, as illustrated in Figure 24 above.

In addition, the *Edit User* page can be used to disable user accounts. To disable a user account, select the user account name from the enabled account list and click the “Disable User” button on the *Edit User* page as illustrated in Figure 24 above. A disabled account cannot be used to log in to POCA, but all data associated with the disabled user will be preserved.

Similarly, the *Edit User* form for the disabled user account can be used to enable user accounts. To enable the disabled user account, select the account from the disabled account list and click the “Enable User” button on the *Edit User* page.

4.2 Add/Edit News Items

News Items display on the home page of the POCA system under the News section as illustrated in Figure 25 below. Existing news items can be edited, and additional news items can be created by clicking the “Add/Edit News Items” link in the list of *Advanced Settings* on the *Settings* screen. To add a news item, populate the *Headline*, *News Teaser*, *News Item*, and *Expire Date* fields in the form that appears below, and click the “Submit/Update” button. Click “Reset” to clear the form.

Figure 25: Add/Edit News Item page

The fields on this form are described below table.

Field Name	Definition/Description	Field Type
Headline	This is the title that will identify the news item. This field Is required.	Edit
News Teaser	Text entered here will appear below the headline on the home and login pages. This field is required.	Edit

News Item	This is the main text of the news item. This field is required.	Edit
Expire Date	The expire date determines when a news item will no longer be displayed on the home and login screens. Enter a date in the format MM-DD-YYYY. This field is required.	Edit

To edit an existing news item, select a news item in the drop down list at the top of the screen, and click the ‘*Get News Item*’ button as illustrated in Figure 26 below. Edit the information that appears in the form, and click “Submit/Update” when you are satisfied with the information you entered.

Welcome Admin Admin. Today is 10-01-2019

FDA **POCA 4.3**
Phonetic and Orthographic Computer Analysis

[Return to Settings](#)

Select a news Item from the list to edit it: POCA Version 4.3

Headline: POCA Version 4.3

News Teaser: POCA Version 4.3 is deployed

News Item: POCA Version 4.3 is deployed.

Expire Date: 10-30-2019

News Item Added/Saved.

Figure 26: Edit a News Item

4.3 User Access Report (UAR)

Administrator users can view a list of all users, enabled users and disabled users with their full name, e-mail addresses, status, and user group assignment from this feature.

Administrators can export the user’s list into a Microsoft Excel spreadsheet by clicking on the ‘Export to Excel’ button as illustrated in Figure 27 below. Administrators can also filter user’s lists for a specific time frame.

Welcome Admin Admin. Today is 10-01-2019

POCA 4.3
Phonetic and Orthographic Computer Analysis

[Return to Settings](#)

User Access Report

Enter Begin Date: (mm/dd/yyyy)

Enter End Date: (mm/dd/yyyy)

All **Enabled** **Disabled**

Total All Users: 1

User Name	Full Name	Email	User Group	Status	Create/Update Date
Admin	Admin Admin	youremail@domain	System Administrators	Enabled	08/07/2019

Figure 27: UAR Report

4.4 Change the Password Policies

Administrator users can change the password policies as shown in Figure 28 below.

Welcome Admin Admin. Today is 10-01-2019

POCA 4.3
Phonetic and Orthographic Computer Analysis

[Return to Settings](#)

Number of required special characters (!@#\$\$%^&*):

Minimum length of password:

Number of days until passwords are required to change:

Minimum number of days before password can be changed:

Number of allowed login attempts:

Number of changed passwords to be kept in history:

Figure 28: Change the Password Policies

4.5 Edit Account Request Email Address

When a user account is requested, an automatically generated email is sent to the *account request email address* stored in the POCA database. This email address can be changed using the “*Edit Account Request Email Address*” link in Settings page. It will display the page as shown in Figure 29 below.

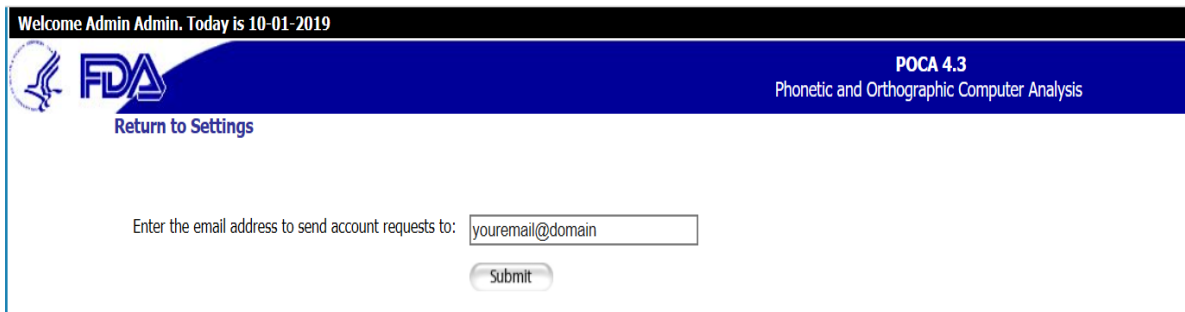


Figure 29: Edit Account Request Email Screen

To have POCA send account requests to multiple email addresses, enter the email addresses separated by semicolons (;). Click “Submit” to store your changes to the POCA database.

4.6 Edit Feedback Email Address

When a user fills out and submits the *Comments and Feedback* form, POCA will send an automatically generated email to the *Feedback Email Address* stored in the database. This email address can be changed using the “*Edit Feedback Email Address*” link in Settings page. It will display the page as shown in Figure 30 below.



Figure 30: Edit Feedback Email Address Screen

To have POCA send feedback and comments to multiple email addresses, enter the email addresses separated by semicolons (;). Click “Submit” to store your changes to the POCA database.

5 Advanced Settings – System Administrators

5.1 Data source Maintenance

For users designated as *System Administrators*, the POCA system supports capability to identify, load, refresh, and delete data sources from the POCA database. The data access process begins with the *Data source Maintenance* screen, as illustrated in Figure 31 below, which can be accessed by clicking the “Data source Maintenance” link in the *Advanced Settings* section of the *Settings* page.

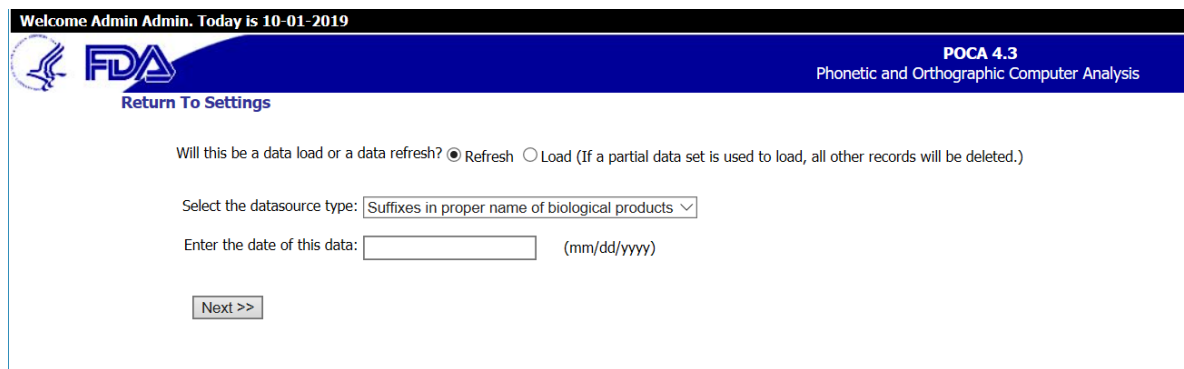


Figure 31: Data Source Maintenance Screen

Select the Data Source type, enter the date of the data in the format “MM-DD-YYYY”, and check if you wish to load or refresh the data source. Click the “Next” button, and follow the directions provided.

5.2 Modify Data source Names

To rename a Data Source in the POCA database and also to add new data sources, click on the “Modify Datasource Names” link in the *Advanced Settings* section of the *Settings* page.. The datasource name screen appears as illustrated in Figure 32 below.. Select the “Edit” button to the left of the Data source Name that you wish to edit. Once the name change is complete, make sure to select the “Update” button to successfully update the data.

Welcome Admin Admin. Today is 10-01-2019

POCA 4.3
Phonetic and Orthographic Computer Analysis

[Return To Settings](#)

Select the "Edit" button to the left of the Datasource Name that you wish to edit. Once the name change is complete, make sure to select the "Update" button to successfully update the data.

Datasource Name	
Edit	Suffixes in proper name of biological products
Edit	Drugs At FDA
Edit	RxNorm
Edit	United States Adopted Names

Add a new datasource:

Figure 32: Modify Data Source names

6 Advanced Settings – Business Administrators

6.1 Delete Drug Name

To delete a drug name from the POCA database, click the “*Delete Drug Name*” link under *Advanced Settings* in Settings page. The first screen in the *Delete a Record* wizard, shown in Figure 33 below, allows business administrators to search for a drug name record in the POCA database. Enter the name of the drug you wish to delete in the text box provided and click the “Search” button. In the sample below, we searched for the name *lipitor*.

Return to Settings

Search for the record you would like to delete using the search box below. Once you have found the record you are looking for, select it by clicking the circle next to the name and then clicking the next button.

Search:

(Use % for wildcard searching or _ for single character searching)

Figure 33: Delete a Record Screen (1 of 2)

Our search returns a list of records composed of drug names and their associated data sources, as shown in the screen capture in Figure 34 below.



Search for the record you would like to delete using the search box below. Once you have found the record you are looking for, select it by clicking the circle next to the name and then clicking the next button.

Search:

(Use % for wildcard searching or _ for single character searching)

Name	Datasource
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input checked="" type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	Drugs At FDA

Figure 34: Delete a Record Screen (2 of 2)

Find the record you wish to delete and mark it for deletion by clicking the radio button to the left of the drug name. Click the “Delete” button. At the “Delete Confirmation” page, press the “Yes” button to remove the record from the POCA database or “No” button to not remove the record from the POCA database.

6.2 View SE Drug Names

To view the drugs entered by safety evaluators, click on the “View SE Drug Names” link under *Advanced Settings* in Settings page. A screen appears allowing administrators to for any drug name entered over a select period of time as listed in the dropdown menu of the text box as illustrated in Figure 35 below., Select the date range from the drop down and you will see the drug names entered for that date range as illustrated in the figure below.

Select the Date Range you would like to view from the list below.

Show Last Month ▼

Drug Name	Date Entered	Entered By
Abasria	6/3/2013 1:30:04 PM	Walter Fava
Actidate	6/3/2013 1:32:30 PM	Walter Fava
Aloftyn	6/3/2013 1:29:28 PM	Walter Fava
Avlina	5/31/2013 12:03:26 PM	Walter Fava
Cerinta	6/3/2013 1:31:17 PM	Walter Fava
Elifemme	6/3/2013 1:31:02 PM	Walter Fava
Hemangiol	6/3/2013 1:32:13 PM	Walter Fava
Jarbina	5/31/2013 6:59:35 AM	manizheh siahpoushan
Levemir FlexTouch	6/3/2013 2:07:37 PM	Walter Fava
Lorseva	6/3/2013 1:33:01 PM	Walter Fava
Mitigo	6/3/2013 2:06:28 PM	Walter Fava
Novolog FlexTouch	6/3/2013 2:07:16 PM	Walter Fava

Figure 35: View SE Drug Names screen

7 Drug Name Searches - All Users

7.1 Search Algorithms

The POCA system has three search modules, namely *orthographic*, *phonetic*, and *text*.

The orthographic similarity score is calculated using an ALINE algorithm modified for orthographic purposes. The orthographic search engine does not accept wild cards, as the algorithm takes each part of a written name into account when matching against names stored in the POCA database. The orthographic search algorithm was updated in POCA 4.0 to place a greater search weight to the beginning letters of names. The update has been tested thoroughly by FDA team.

The phonetic similarity score is calculated using an ALINE algorithm for phonetic matching. The phonetic search engine does not accept wild cards because each sound of a name is taken into account when matching against names in the POCA database. The phonetic search engine ignores the numeric and special characters in the drug name.

The combined score is calculated as the average of the orthographic and phonetic scores.

Note that both the orthographic and phonetic search engines ignore numeric and special characters included in drug names. For example, the orthographic and phonetic similarity score for ‘Drug-2’ and ‘Drug-25’ will be 100%. Examples are provided in Figure 36 below.

Direct Search	
Candidate Drug:	tylenol
Comparator Drug:	tylenol @\$45
<input type="button" value="Reset"/> <input type="button" value="Submit"/>	
Combined Score:	100
Phonetic Score:	100
Orthographic Score:	100

Direct Search	
Candidate Drug:	Otezla
Comparator Drug:	Otezla 4566
<input type="button" value="Reset"/> <input type="button" value="Submit"/>	
Combined Score:	100
Phonetic Score:	100
Orthographic Score:	100

Figure 36: Direct Search

The text search module allows users to search for exact text matches using a text matching code built into an Oracle Database Management System. Several wildcards are available for the text search engine as explained below.

The percent sign (%) is a wildcard character that will match any sequence of consecutive characters.

For example:

Search Term: flo%in

Results: floucin, floxin

The underscore character (_) is a wildcard that will match any single character.

For example:

Search Term: flo_in

Results: floxin

Wildcard characters can be used in conjunction with each other for matching a wider variety of patterns.

For example:

Search Term: fl%x__

Results: flexin, flexon, floxin, fluaxol, flavocoxid

In the above wildcard example, both types of wild cards were used. A '%' character was used to match any sequence of characters after the letter 'l' character and before the letter 'x' character in the search term. Two underscore characters ('_') were used to match any two (2) characters at the end of a name.

7.2 Accessing the Search

The “*Drug Name Search*” section in Home page provides an easy interface to conduct searches in POCA. The Search page can also be accessed by clicking the “*Search*” link in the Navigation Bar or by clicking the “*New Search*” link in the *Options Bar*.

The “*Direct Search*” functionality is available to all users under “Direct Search” section in Home page as well as in Search page. This feature provides users the ability to do direct searches between a Candidate Drug name and a Comparator Drug name. After entering those 2 drug names and pressing Submit button, the Combined, Phonetic and Orthographic score search results will be displayed for the candidate and comparator drug names.

7.3 Search View

The “*Drug Name Search*” view allows users to search the POCA drug databases for a drug name using a combination of Orthographic, Phonetic, and Text algorithms. The *Drug Name Search* is accessible directly from the Home page, or by clicking on the “Search” link in the header.

By default, orthographic and phonetic search type boxes are checked and will run both an orthographic and phonetic search automatically without the user manually checking those search type boxes. The USAN Stem Search box is also checked by default and will run once the search is submitted. However, users may also tailor search types by checking or

unchecking any one or any combination of the orthographic, phonetic, text, and USAN stem searches which appear on the Drug Name Search screen as illustrated in Figure 37 below. When performing a text search, the underscore ‘_’ character may be used to match any single character or the percentage ‘%’ character may be used to match any string of characters.

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type: ☒ Orthographic ☒ Include USAN Stem Search
☒ Phonetic
☐ Text*

Datasources:

	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	Drugs At FDA	07-25-2019	21,467	
<input checked="" type="checkbox"/>	RxNorm	07-09-2019	28,850	
<input type="checkbox"/>	Suffixes in proper name of biological products	08-29-2019	49	
<input type="checkbox"/>	United States Adopted Names	09-09-2019	608	

USAN Stem Datasources:

	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	United States Adopted Names	09-09-2019	608	

Figure 37: Drug Name Search

By default, the drug name search will run against the Drugs At FDA and RxNorm datasources. You may choose by checking or unchecking any combination of the datasources you wish to include in your search.

Enter the drug name to search in the “Search” Textbox and click on the “Submit” button or press “Enter” key. The “Reset” button is provided to clear the Search Text field and start a new search with the original default settings.

The search results will be calculated and filtered with the scores that are equal to and greater than the “user’s results threshold” value. The “Search Results” page will display in a results table with pagination and an “Export to Excel” button.

7.4 Search Results

The *Search Results* page displays the results of every search. It displays a table containing drug names that matched the search criteria for every search type specified in the search.

Note that if the phonetic and orthographic search types are specified for the search, the results will display in a table that contains tabs which will allow users to display scores for each search type separately for the ‘combined’ results, ‘phonetic’ results, and ‘orthographic’ results. There is also a tab that allows user to display all three types of search results on one page. An overview of the result tabs is illustrated in Figure 38 below. It shows the *Search Results* page displaying the results of a search for *lipitor* using the orthographic and phonetic search types.

Welcome Admin Admin. Today is 10-01-2019

FDA

POCA 4.3
Phonetic and Orthographic Computer Analysis

New Search

Search Results
Search Term: *lipitor*

Export To Excel Advanced Export to Excel

Combined **Phonetic** Orthographic All USAN Stem

Orthographic & Phonetic Matches greater than 50%: Results 1 - 20 of 314
70% and Higher: 5 Between 55% and 69%: 108 54% and Lower: 201

Name of Concern	Match % -	Datasource
LIPITOR	100	RxNorm; Drugs At FDA
LIPIDRO	78	RxNorm
LIPIDIL	72	Drugs At FDA
LIPIODOL	70	RxNorm
LIPJODOL	70	Drugs At FDA
EPITOL	68	RxNorm; Drugs At FDA
ZADITOR	68	RxNorm; Drugs At FDA
ZIPSOR	68	RxNorm; Drugs At FDA
CLINITAR	66	RxNorm
EPICORT	66	Drugs At FDA
KALBITOR	66	RxNorm; Drugs At FDA
LIDOCORT	66	RxNorm
LIDOPRO	66	RxNorm
RELISTOR	66	RxNorm; Drugs At FDA
DOMITOR	65	RxNorm
FLECTOR	64	RxNorm; Drugs At FDA
GLISTER	64	RxNorm
LACTITOL	64	RxNorm
LEVITRA	64	RxNorm; Drugs At FDA
LIDOMAR	64	RxNorm

Figure 38: Search Results Example

For searches that include a ‘Text’ search type, the Search Results page will display with a tab at the top of the table containing exact text matches.

All table columns on the *Search Results* page can be sorted by clicking on the column header.

Users can view product characteristic information for names on the search results page by putting the cursor over each name and left clicking on the drug name of concern. A “Product Details” page will be displayed in new window . The Product Details page will be similar to image provided in Figure 39 below. Please be aware that some results identified from RxNorm will not contain any information in Product Details page.

Name of Concern	Orthographic Score	Data Sources	Active Ingredient	Strength	Dosage Form	Route
Otezla	100	RxNorm; Drugs At FDA	APREMILAST	10MG 20MG 30MG	TABLET	ORAL
Zotex La	85	RxNorm				
Telazol	81	RxNorm	TILETAMINE 50 MG/ML / ZOLAZEPAM 50 MG/ML INJECTABLE SOLUTION [TELAZOL]			
Terazol 3	77	RxNorm; Drugs At FDA	TERCONAZOLE	0.80% 80MG	CREAM SUPPOSITORY	VAGINAL
Terazol 7	77	RxNorm; Drugs At FDA	TERCONAZOLE		0.40% CREAM	VAGINAL
Oxtellar	75	RxNorm	24 HR OXCARBAZEPINE 150 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR] 24 HR OXCARBAZEPINE 300 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR] 24 HR OXCARBAZEPINE 600 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR]			

Figure 40: Export to Excel examples

When users click on the 'Export to Excel' button, a pop up window appears at the bottom of the screen asking if you want to open or save your search results. Click on the dropdown arrow next to the 'Save' tab, then select 'Save as' from the dropdown menu and the data will be saved in a

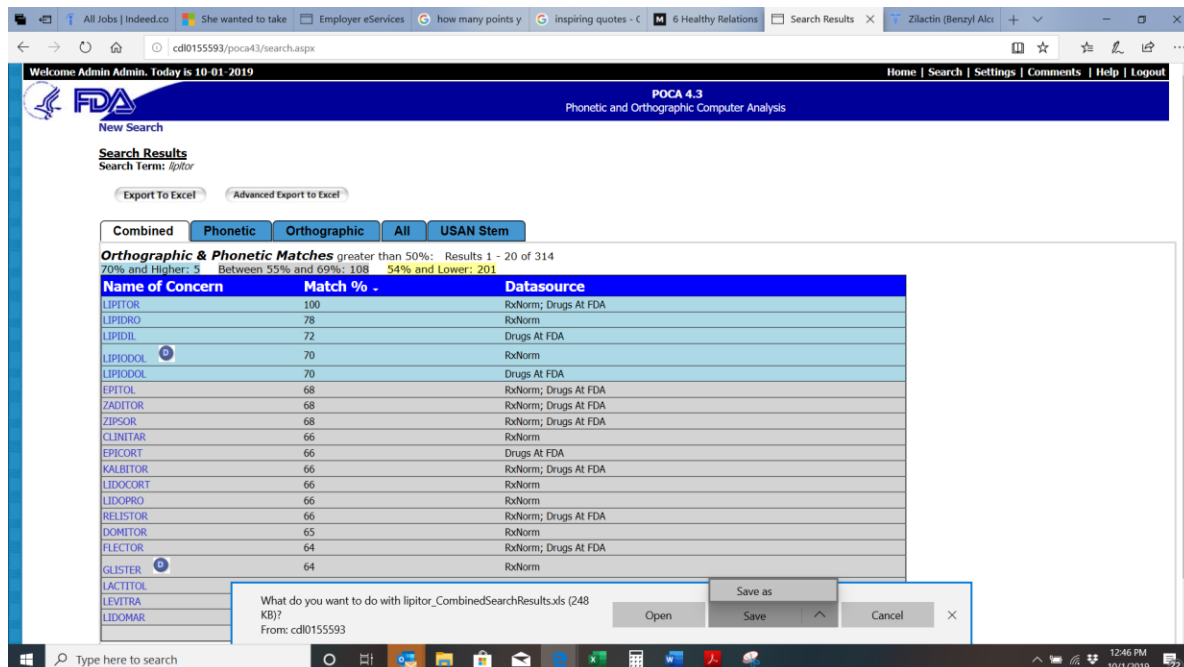


Figure 41: Excel file 'Save as' in the local drive

file with a '.xls' extension appearing after the file name. This format will allow you to

easily edit the information in your spreadsheet. If you choose only to open the spreadsheet, be aware that when you decide to save it, you will need to click on the ‘File’ tab in the upper left hand corner of toolbar, select ‘Save as’ and from the dropdown menu, choose the version of Excel with the file extension, ‘.xls’ or ‘xlsx’.

8. USAN Loading file Procedures to POCA 4.3

In order to upload the USAN data to POCA 4.3, go to settings in the tool bar of the home page and under Advanced Settings click on “Datasource Maintenance” as shown in Figure 42 below. A new webpage will open with a text field labeled, ‘Select datasource type’ as illustrated in Figure 43 below.. Using the dropdown menu, select the United States Adopted Names datasource.

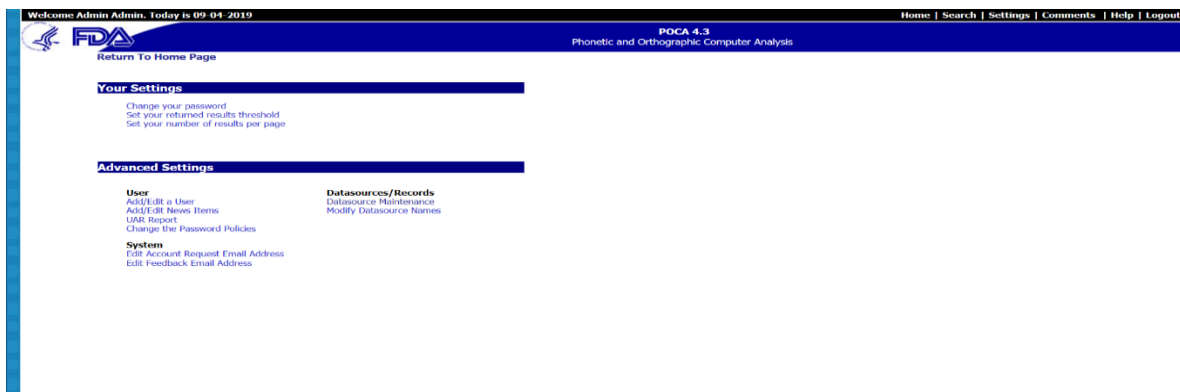


Figure 42: POCA Setting screen for System Administrator

In figure 43, we will select the United States Adopted Names as Data Source type, select Load radio button and also, we enter the Date for the data (e.g. 06/29/2019) and click on Next Button to pen the next webpage to select the DataSource file.

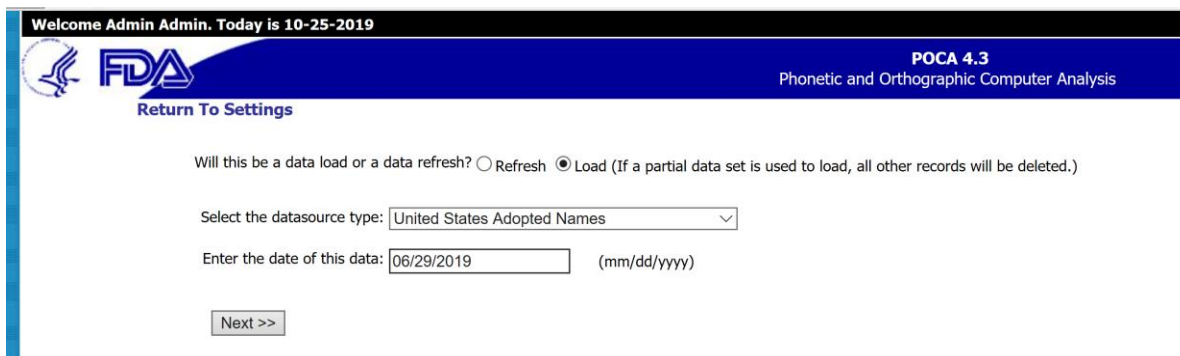


Figure 43: USAN Data load Webpage

In figure 44 (Datasource display webpage), we chose the “Usan-20190628-New.txt file from the data sources list as shown in the figure 40 below.

Select the file that will be used to refresh/load the datasource.

File Name	File Size	File Date
cbersuffix_013119_New.txt	1 KB	02-14-2019
cbersuffix_013119_New.zip	1 KB	02-26-2019
cbersuffix_071019_New.txt	2 KB	07-10-2019
datafiles_public_version.zip	14 KB	09-04-2019
data_source_template.txt	3,308 KB	09-05-2017
drugsatfda_20101031_New.txt	3,854 KB	11-14-2016
drugsatfda_20170108_New.txt	3,888 KB	01-26-2017
drugsatfda_20170224_New.txt	KB	05-08-2017
drugsatfda_20170826_New.txt	4,053 KB	09-10-2017
drugsatfda_20170928_New.txt	4,041 KB	10-02-2017
drugsatfda_20180127_New.txt	4,116 KB	03-20-2018
drugsatfda_20190124_New.txt	4,354 KB	04-08-2019
drugsatfda_20190124_New.zip	513 KB	02-26-2019
drugsatfda_20190207_New.txt	4,368 KB	04-12-2019
drugsatfda_20190725_New.txt	4,440 KB	07-25-2019
orangebook_20170120_New.txt	4,326 KB	01-26-2017
POCA_DPD.txt	36,964 KB	04-28-2017
rnorm_20101110_New.txt	4,625 KB	11-30-2016
rnorm_20170117_New.txt	4,604 KB	01-26-2017
rnorm_20170208_New.txt	KB	05-08-2017
rnorm_20170812_New.txt	4,691 KB	09-10-2017
rnorm_20170917_New.txt	4,666 KB	10-02-2017
rnorm_20170918_New.txt	2 KB	03-29-2019
rnorm_20180117_New.txt	4,696 KB	03-20-2018
rnorm_20190108_New.txt	4,471 KB	04-12-2019
rnorm_20190108_New.zip	483 KB	02-26-2019
rnorm_20190709_New.txt	4,467 KB	07-09-2019
FOSTUDY_01232017.dmp	556,928 KB	01-23-2017
suffix_20190131_New.txt	2 KB	03-29-2019
suffix_20190329_New.txt	1 KB	04-12-2019
usan_20190222_New.txt	39 KB	04-12-2019
usan_20190628_New.txt	42 KB	07-10-2019

Figure 44: Datasource display webpage

After clicking on selected Data source file (“Usan-20190628-New.txt”), the webpage with question will appear that it asked you “Do you want to continue refreshing/loading this DataSource?” “and you click on “Yes” to proceed with loading the selected Data Source.

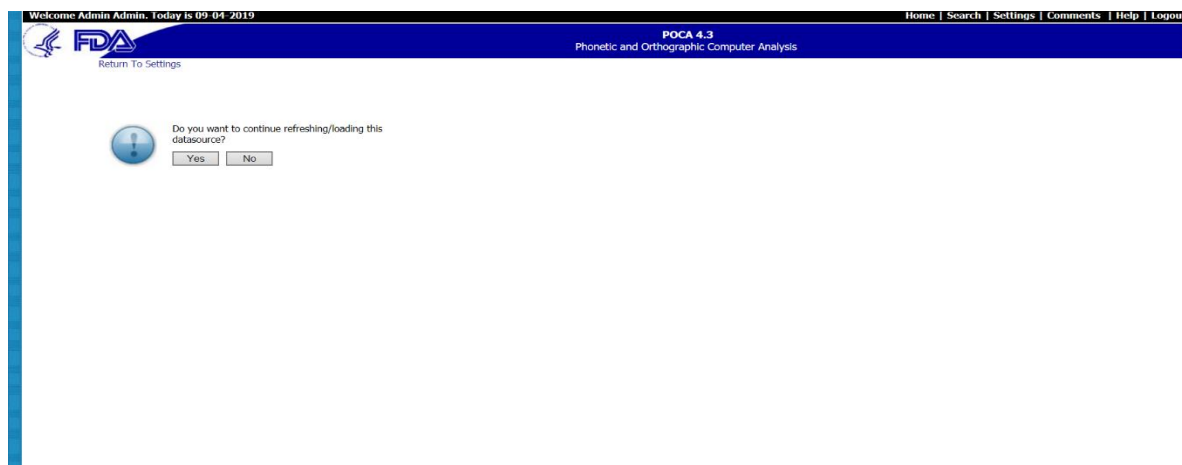


Figure 45: Refreshing/loading Data Source Question webpage

After click on “Yes” to proceed with loading the selected Data Source, the below webpage (Figure 46) will be appear that shows Refreshing /loading of USAN Data which is dated on 06-28-2019 is in process.

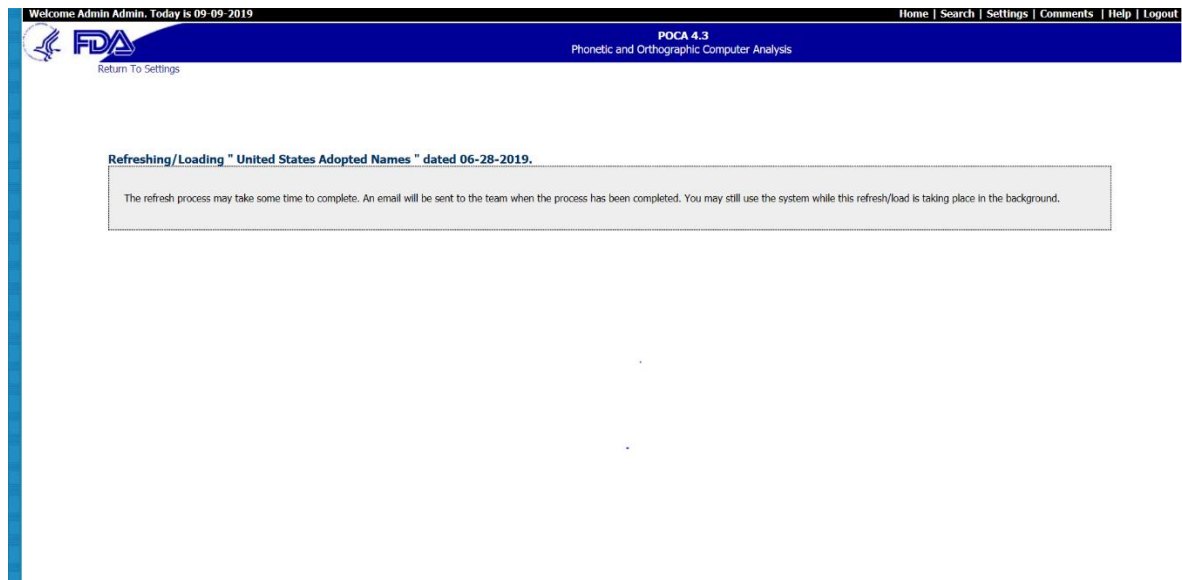


Figure 46: Refreshing/loading Data Source in process webpage

After loading Datasource, when we go to POCA 4.3 home page, we will see the USAN Datasource added to Datasource section in homepage as shown in the Figure 47.

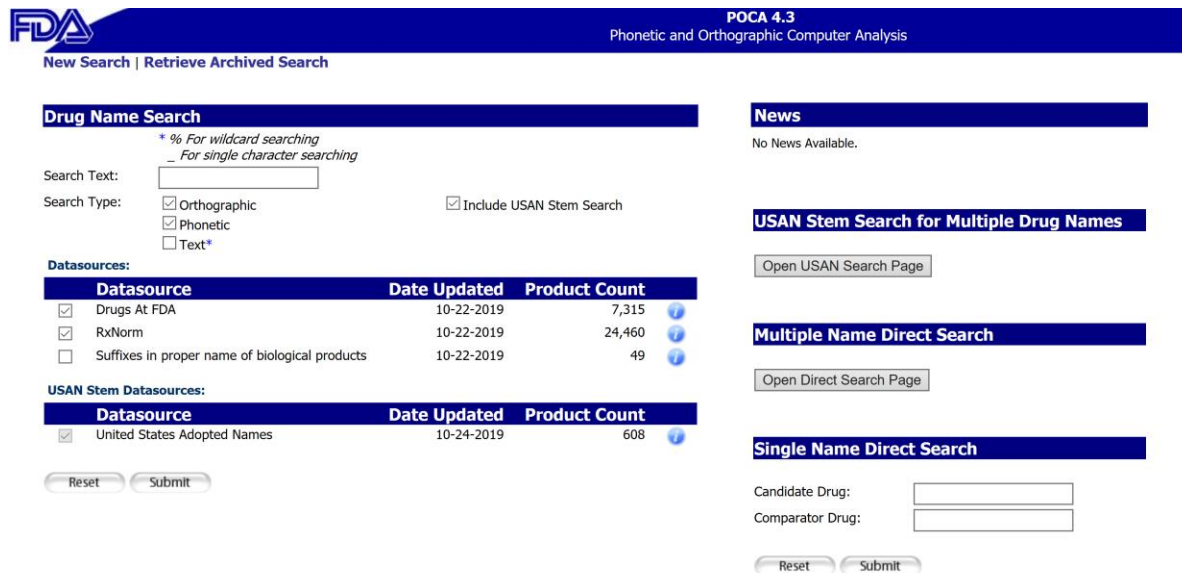


Figure 47: Home webpage included USAN (United States Adopted Names) Datasource

NOTE: This data load processes applies for all other data sources